DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

#24

JAN 6 2000

Re: Maxalt®
Docket No.: 98E-0852

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 5,298,520, filed by Merck & Co., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Maxalt®, the human drug product claimed by the patent.

The total length of the regulatory review period for Maxalt® is 2,099 days. Of this time, 1,734 days occurred during the testing phase and 365 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 1, 1992.

   FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on October 1, 1992.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: June 30, 1997.

   FDA has verified the applicant's claim that the new drug application (NDA) for Maxalt ® (NDA 20-864) was initially submitted on June 30, 1997.

3. The date the application was approved: June 29, 1998.

FDA has verified the applicant's claim that NDA 20-864 was approved on June 29, 1998.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Philippe L. Durette
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